

### Remarks

The June 28, 2005 Official Action has been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, it is noted that a shortened statutory response period of three (3) months was set in the June 28, 2005 Official Action. Therefore, the initial due date for response is September 28, 2005.

The Examiner has objected to the figures "because several are difficult to read." The instant application is a divisional application of U.S. Patent Application 09/828,648, now U.S. Patent 6,689,877. Applicants note that the figures of U.S. Patent Application 09/828,648, which are the same as the figures presented in the instant application, were found to be acceptable for publication. Additionally, the Examiner has failed to identify those figures which are allegedly "difficult to read" nor the reasons why the drawings fail to comply with 37 C.F.R. §1.84. Accordingly, Applicants cannot effectively address the concerns of the Examiner. However, in an effort to be responsive to the Examiner's request, Applicants submit herewith new copies of all of the figures. Applicants respectfully request that should the Examiner maintain his position regarding the drawings, the Examiner expressly indicate which figure(s) is objected to and what standard under 37 C.F.R. §1.84 the figure(s) allegedly fail to satisfy in order to assist Applicant in the correction of any perceived defect.

Additionally, the Examiner contends that Figure 5A lacks sequence identifiers. Applicants have inserted the appropriate sequence identifiers into the figure legend of Figure 5A. In light of the foregoing, Applicants respectfully request the above objection to the Figure 5A be withdrawn.

The Examiner has also objected to the title for allegedly not being indicative of the invention to which the

claims are directed. Applicants have replaced the title with a more descriptive title of the invention instantly claimed. Accordingly, Applicants respectfully request that the instant objection be withdrawn.

Claims 8-10 have been rejected under 35 U.S.C. §102(b) as allegedly anticipated by U.S. Patent 5,831,058 (hereinafter the '058 patent).

Lastly, the Examiner has rejected claims 11-13 under 35 U.S.C. §103(a) as allegedly unpatentable over the '058 patent in view of Harlow et al. (Antibodies: A Laboratory Manual (1988) Cold Spring Harbor Laboratory, page 353).

The foregoing objections and rejections constitute all of the grounds set forth in the June 28, 2005 Official Action for refusing the present application.

In accordance with the instant amendment, claims 16-18 have been added. Support for new claims 16-18 can be found, for example, in original claims 11-13 and at page 30, line 23 to page 31, line 7. No new matter has been introduced into this application by reason of any of the amendments presented herewith.

In view of the present amendment and the reasons set forth in this response, Applicants respectfully submit that the objections to the drawings, the objection to the title, the 35 U.S.C. §102(b) rejection of claims 8-10, and the 35 U.S.C. §103(a) rejection of claims 11-13, as set forth in the June 28, 2005 Official Action, cannot be maintained. These grounds of rejection are, therefore, respectfully traversed.

**CLAIMS 8-10, AS AMENDED, ARE NOT ANTICIPATED BY  
U.S. PATENT 5,831,058**

The Examiner has rejected claims 8-10 under 35 U.S.C. §102(b) as allegedly anticipated by the '058 patent. Specifically, it is the Examiner's position that the '058 patent teaches how to make polyclonal and monoclonal antibodies to OTK18, which is another name for NEBR1.

Applicants respectfully disagree with the Examiner. In order to constitute evidence of lack of novelty under 35 U.S.C. §102(b), a prior art reference must identically disclose each and every element of the rejected claim. In re Bond, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). Notably, no antibodies having affinity for OTK18 are described in the '058 patent. However, in the interest of expedited prosecution, Applicants have amended claim 8, from which claims 9 and 10 depend, to recite antibodies immunologically specific for NEBR1 fragments consisting of amino acids 1-115, 1-241, 1-300, and 58-115 of SEQ ID NO: 2. Support for this amendment can be found throughout the specification. For example, at page 11, lines 22-24, the instant specification discloses that NEBR1 fragments are "useful for raising antibodies to a portion of the NEBR1 amino acid sequence." Furthermore, at page 30, lines 13-22, the specification discloses that "purified NEBR1, or fragments thereof, may be used to produce polyclonal or monoclonal antibodies." A fragment is defined at page 11, lines 17-22 as a "stretch of amino acid residues of ... most preferably, at least twenty to thirty or more contiguous amino acids."

The instant specification discloses several fragments of NEBR1. In particular, the specification discloses three truncated NEBR1 proteins consisting of amino acids 1-115, 1-241, and 1-300 of SEQ ID NO: 2 (see, e.g., page 3, lines 8-25) which were capable of repressing transcriptional expression to levels similar to that of wild-type NEBR1 (see, e.g., page 48, lines 1-4 and Figure 4D). The specification also discloses the fragment consisting of amino acids 58-115 as being responsible for the suppression function of NEBR1 (see, e.g., page 48, lines 4-6). Accordingly, Applicants submit that the instant amendments to claim 8 are fully supported by the instant specification.

The Examiner contends that the '058 patent discloses the OTK18 gene in Example 4 at columns 14 to 16. The '058

patent allegedly describes producing polyclonal or monoclonal antibodies to the proteins described in the patent (column 3, lines 53-60). Specifically, the '058 patent discloses producing a protein of the patent in large quantities to use as an antigen (column 3, lines 54-57) for antibody production. Applicants note that the '058 patent fails to teach the use of fragments of OTK18 (NEBR1) for antibody production and fails to teach or suggest the particular NEBR1 fragments instantly claimed. Notably, these fragments of NEBR1 present different epitopes to the immune system for antibody production than the full-length NEBR1 protein.

In light of all of the foregoing, Applicants submit that the '058 patent fails to teach each and every element of the instantly claimed antibodies. Accordingly, Applicants respectfully submit that the rejection of claims 8-10 under 35 U.S.C. §102(b) is untenable and should be withdrawn.

**CLAIMS 11-13, AS AMENDED, ARE NOT RENDERED OBVIOUS BY LIND  
U.S. PATENT 5,831,058 IN VIEW OF HARLOW ET AL.**

The Examiner has also rejected claims 11-13 under 35 U.S.C. §103(a) as allegedly unpatentable over the '058 patent in view of Harlow et al. (Antibodies: A Laboratory Manual (1988) Cold Spring Harbor Laboratory, page 353). Specifically, the Examiner contends that it would have been obvious for a skilled artisan to couple the detectable labels taught by Harlow et al. to the antibodies taught by the '058 patent in order to detect the expression of NEBR1, as instantly claimed.

As stated hereinabove, Applicants have amended claim 8 to recite that the claimed antibodies are immunologically specific for particular fragments of NEBR1. Applicants have also amended claim 11 to recite that the antibodies employed in the recited method are the antibodies of claim 8. For the reasons set forth above, Applicants submit the '058 patent fails to teach or suggest antibodies directed to the NEBR1

fragments recited in claim 8. Inasmuch as the '058 patent and Harlow et al. fail to teach or suggest the antibodies used in the method of claim 11, Applicants submit that the instant rejection of claim 11 and dependent claims 12 and 13 is untenable.

For completeness, Applicants also submit that the '058 patent is silent as to the detection of NEBR1 expression in HIV-1 infected cells as recited in newly added claims 16-18. It is a well-settled premise in patent law that "silence in a reference is not a proper substitute for adequate disclosure of facts from which a conclusion of obviousness may justifiably follow." In re Burt, 148 U.S.P.Q. 548 (CCPA 1966). Accordingly, Applicants also submit that it cannot be reasonably held that new claims 16-18 are unpatentable over the '058 patent in view of Harlow et al.


In light of all of the foregoing, Applicants respectfully request that the rejection of claims 11-13 under 35 U.S.C. §103(a) be withdrawn.

#### **CONCLUSION**

In view of the amendments and replacement drawings presented herewith, and the foregoing remarks, it is respectfully urged that the objections and rejections set forth in the June 28, 2005 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone interview, the Examiner is requested to telephone the undersigned attorney at the phone number give below.

Respectfully submitted,  
DANN, DORFMAN, HERRELL AND SKILLMAN  
A Professional Corporation

By   
Robert C. Netter, Jr., Ph.D.  
PTO Registration No. 56,422

Telephone: (215) 563-4100  
Facsimile: (215) 563-4044  
Enclosure: 18 sheets of Replacement Drawings